

**REMARKS**

Applicants herein have deleted the first paragraph of the specification to remove the priority claims to the provisional applications. Applicants have also requested a Corrected Filing Receipt that no longer makes reference to these provisional applications. It is believed that no new oath or declaration is necessary to disclaim the priority claims to these provisional applications.

The specification has also been amended to correct the sequence identifiers in the specification so that they correspond to those listed in the attached Sequence Listing. Specifically, the sequence shown for SEQ ID NO: 36 on page 218 of the specification is identical to that of SEQ ID NO: 72 listed in the original Sequence Listing. Thus, the sequence identifier SEQ ID NO: 36 in the specification was amended to SEQ ID NO: 72. Additionally, the sequences identified in the specification as SEQ ID NOs. 36-45 (pages 446-447, 476-477, 479, 483, and 486) were inadvertently omitted from the original Sequence Listing. Those omitted sequences were added as SEQ ID NOs: 2268-2277 in the substitute Sequence Listing and the sequence identifiers in the specification were amended accordingly. Thus, no new matter has been added.

In the instant application, claims 1-4, 13-17, 19 and 20 are under consideration. Claims 5-12 and 21-29 have been cancelled as being directed to non-elected inventions. Claim 18 has also been cancelled in favor of claim 17. Claims 1-4 have all been amended to change the recitation of "Therapeutic protein:X" to "Therapeutic protein X" in order to conform with the terminology used in the specification. See, for example, Table 1, pages 20-171, left column (reciting "Therapeutic protein X"). Claim 1 has also been amended to define "Therapeutic protein X" as at least one of the proteins

listed in Table 1 of the specification (pages 20-171). Claims 13-14, 17, and 19-20 have also been amended to correct their dependencies so that they are no longer dependent on cancelled claims. Thus, the amended claims are fully supported by the specification.

Each of the issues raised in the Office Action of February 13, 2004, are addressed herein below.

**Incorporation by Reference**

The Office has requested that applicants provide a list of the applications from the 900 patent applications referenced in specification (pages 513-533 of specification) that are related to the elected subject matter.

We request that this requirement be deferred until such time as this application is reviewed, reconsidered, and the examiner has considered whether a further requirement for restriction is appropriate in this application in view of the amendments made to this application. Specifically, in a telephone conference conducted with Examiner Borin by the undersigned on July 21, 2004, the possibility of an additional requirement for restriction was discussed, but Examiner Borin indicated that he would have to consider this reply before making a decision. The telephone conference did not involve a discussion of the merits of the invention or of any outstanding rejection, objection or requirement.

**Claim Objections**

Claims 14-18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Office advised that Applicants either cancel the claims, or amend the claims to place the

claims in proper dependent form, or rewrite the claims in independent form. Applicants respectfully traverse.

Claims 14-18 are product-by-process claims and claims 14-16 require production of the albumin fusion protein in yeast, while claims 17-18 require production in mammalian cells. First, claim 18 has been cancelled in favor of claim 17 and therefore, the objection is moot for these two claims in light of the amendment. Second, claims 14-16 are distinct because the claims require production in a glycosylation-deficient yeast (claim 15) and in a glycosylation and protease-deficient yeast (claim 16), which further limit the yeast required in claim 14. Third, as discussed below, the albumin fusion protein produced by these processes is not the same as that found in the references cited by the Office and therefore, claims 14-17 should be allowable. Therefore, withdrawal of the claim objections is requested.

**35 U.S.C. § 102 Rejection**

Claims 1-4 and 13-20 are rejected under 35 U.S.C. 102(b) as anticipated by Ballance et al (WO 9724445) or Yeh et al (US 5665863) or Becquart et al (WO 95/30759) or Becquart et al (EP 41 3622 or US 6165470).

The Office alleges that Ballance et al ( WO 9724445) teaches fusion proteins of albumin and growth hormone, or fusions of variants of either, that are secreted by yeast and have increased serum and storage stability. The Office also alleges that Yeh et al (US 5665863) teaches fragments of G-CSF that are conjugated with albumin to increase their stability. The Office additionally alleges that Becquart et al (WO 95/30759) teaches biologically active polypeptides that have the biological active domains of a protein inserted into an albumin. The Office further alleges that Becquart

et al (EP 413622 or US 6165470) teaches albumin-viral receptor fusion proteins, in particular, an albumin-CD4 fragment fusion protein.

A finding of anticipation under 35 U.S.C. § 102 requires that “each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987). This standard precludes any finding of anticipation of the instant claims by Ballance et al (WO 9724445), Yeh et al (US 5665863), Becquart et al (WO 95/30759), or Becquart et al (EP 41 3622 or US 6165470).

The Office has interpreted “Therapeutic protein X” as encompassing any “protein or fragments thereof connected to albumin.” See Office Action, page 5. However, independent claim 1, from which all other claims depend, has been amended to recite that “Therapeutic protein X of (a) to (k) is selected from at least one of the proteins set forth in Table 1.” None of the references disclose an albumin fusion protein comprising any one of the specific Therapeutic protein Xs listed in Table 1 (pages 20-171). Thus, none of the references anticipate the instant claims.

Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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